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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|------------------|---------------------------|-------------------------|------------------|
| 10/048,123 | 12/03/2001 | Paul David James Blackler | P32292 | 2730 |
| 20462 759 | 90 10/03/2003 | | EXAMI | NER |
| | E BEECHAM CORPOR | ROBINSON, BINTA M | | |
| CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939 | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| | | | DATE MAILED: 10/03/2003 | [6 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| P | | | | | |
|---|-------------------------|--|--|--|--|
| | Applicati n No. | plicati n No. Applicant(s) | | | |
| | 10/048,123 | BLACKLER ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Binta M. Robinson | 1625 | | | |
| The MAILING DATE of this communication appears on the c ver sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | |
| 1) Responsive to communication(s) filed on | <u> </u> | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ Thi | is action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims , , | | | | | |
| 4) ☐ Claim(s) 15-22 and 25-41 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) 15 and 25-35 is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>16-22 and 36-41</u> is/are rejected. | | | | | |
| 7) Claim(s) 10-22 and 30-47 Israile rejected. | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a)⊠ All b)□ Some * c)□ None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15 | 5) Notice of Informal | y (PTO-413) Paper No(s) Patent Application (PTO-152) | | | |

Detailed Action

The 103 (a) rejections of claims 15-24, 27, 32, 33, and 34 and the 112, second paragraph rejection of claim 23 are withdrawn in light of applicant's amendment at paper no. 13.

(old rejections and objections)

Applicant is advised that should claim 22 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 23 be found allowable, claim 24 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim(s) 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. Claim 16 recites the limitation "Figure I" in line 2, page 2 of the amendment 10B.

 There is insufficient antecedent basis for this limitation in the claim.
- B. Claim 17 recites the limitation "Figure II" in line 2, page 2 of the amendment 10B.

 There is insufficient antecedent basis for this limitation in the claim.
- Claim 18 recites the limitation "Figure III" in line 2, page 2 of the amendment10B. There is insufficient antecedent basis for this limitation in the claim.
- D. Claim 19 recites the limitation "Table I" in line 2, page 2 of the amendment 10B.

 There is insufficient antecedent basis for this limitation in the claim.
- E. Claim 20 recites the limitation "Figure IV" in line 2, page 2 of the amendment 10B. There is insufficient antecedent basis for this limitation in the claim.
- F. Claim 21 recites the limitation "Table II" in line 2, page 2 of the amendment 10B.

 There is insufficient antecedent basis for this limitation in the claim.
- G. In claim 22, line 1, page 2, the term "isolated" is indefinite. How isolated is the polymorph?

(new rejections)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 36-41 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Reaction conditions such as the temperature at which step a, b, c occur, and the solvent that is used in step a critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The applicant does not list the temperature at which steps a, b, and c occur in claims 37, 38, does not list the temperature at which steps a, c and d occur in claim 40 and does not list the temperature at which steps a, b, and d occur in claim 41. The solvent used in claims 36, 38, 39, 40 and 41 is not specified.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. In claim 36, lines 3-4, page 5 of the amendment at paper no. 13, the phrase "in a solvent at an elevated temperature" is indefinite. What solvent in step a of the reaction taking place in and at what temperature is step a taking place in?
- B. Claim 36 recites the limitation "recovering the polymorph of the compound according to claim 15" in line 7. There is insufficient antecedent basis for this limitation in the claim.
- C. Claims 37-41 are indefinite because the elevated tempaature in step a in which the compound is prepared into a solution is not defined.

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Claims 15, 25, 26, 27, 28, 29, 30-35 are allowable.

The IDS at paper no. 15 has been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

September 23, 2003

ALAN L. ROTMAN SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

Glan L Rotman

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